HEALTH AND SENIOR SERVICES

HEALTH CARE QUALITY AND OVERSIGHT BRANCH

HEALTH CARE QUALITY AND OVERSIGHT DIVISION

ACUTE CARE FACILITY OVERSIGHT

CERTIFICATE OF NEED AND ACUTE CARE LICENSURE PROGRAM

Hospital Licensing Standards Emergency Department and Trauma Services

Emergency Department Patient Services, Designation of Stroke Centers

Proposed New Rules: N.J.A.C. 8:43G-7A

Proposed Amendment: N.J.A.C. 8:43G-12.7

Authorized By: Fred M. Jacobs, M.D., J.D., Commissioner

Department of Health and Senior Services (with the

approval of the Health Care Administration Board).

Authority: N.J.S.A. 26:2H-1 et seq., specifically 26:2H-12.27.

Calendar Reference: See Summary below for explanation of exception to

the calendar requirements.

Proposal Number: PRN 2006-2.

Submit written comments by March 4, 2006 to:

John A. Calabria, Director

Certificate of Need and Acute Care Licensure Program

New Jersey Department of Health and Senior Services

PO Box 360, Room 403

Trenton, NJ 08625-0360

The agency proposal follows:

## **Summary**

On September 1, 2004, P.L. 2004, c. 136, codified at N.J.S.A. 26:2H12.27 through 12.32, was enacted. The new law, referred to as the "Stroke
Center Act" (Act), requires the Department of Health and Senior Services
(Department) to designate licensed general hospitals that meet certain standards outlined in the Act as stroke centers. In addition, the Act encourages the
Department, in determining whether to grant stroke center designation, to consider whether a hospital seeking designation contracts with insurance carriers that provide coverage through the State Medicaid and FamilyCare programs.

The proposed new rules would implement the provisions of the Act addressing the criteria for designation as either a primary or comprehensive stroke center.

Despite significant advances in stroke diagnosis, treatment and prevention, stroke remains a common disorder, with an estimated 700,000 to 750,000 new and recurrent strokes occurring each year in the United States. With the continued aging of the population, an increased prevalence of this

disorder is likely. In the Act the Legislature found that, "although new treatments are available to improve the clinical outcomes of stroke, many acute care hospitals lack the necessary staff and equipment to optimally triage and treat stroke patients, including the provision of optimal, safe and effective emergency care for these patients."

The Act requires the Department to establish two levels of stroke centers in the State in order to address this "public health need." The Department is to designate as "many acute care hospitals as possible" as primary stroke centers. These centers are "to evaluate, stabilize and provide emergency care to patients with acute stroke and then, depending on the patient's needs and the center's capabilities, either admit the patient and provide inpatient care, or transfer the patient to a comprehensive stroke center."

The Department is also expected to designate some hospitals as comprehensive stroke centers. Comprehensive stroke centers are to provide complete and specialized care to patients who experience the most complex strokes, which require specialized testing, highly technical procedures and other interventions. In addition, these centers would provide education and guidance to affiliated primary stroke centers.

The Department is proposing new rules implementing the provisions of the Act pertaining to designation of hospitals as either primary or comprehensive stroke centers. Although the Act contains detailed criteria for designation, in those areas where further detail is needed to provide guidance to the regulated community, the Department consulted with New Jersey experts in stroke

diagnosis and treatment in developing the proposed new rules. The Department notes that, while there are generally consistent recommendations available from several national organizations regarding standards for primary stroke centers, no comparable consensus standards for comprehensive stroke centers exist at this time. Basic differences between the two types of stroke centers in the levels of care that need to be provided are understood, but, beyond this, the technical standards for comprehensive stroke care programs are dynamic and evolving. The Department is proposing standards that it believes are consistent with the intent of the Act, and the current state of the evolving consensus. The Act permits the Commissioner to modify the technical criteria specified therein to reflect changing clinical standards. Accordingly, the appropriateness of the proposed regulatory standards would be reassessed at periodic intervals in the future.

The proposed new rules and proposed amendment are summarized as follows:

Proposed new N.J.A.C. 8:43G-7A.1 would set forth the scope of the proposed new Subchapter 7A, which would apply to all licensed general hospitals seeking designation to provide stroke services as either a primary stroke center or a comprehensive stroke center in accordance with N.J.S.A. 26:2H-12.27 et seq.

Proposed new N.J.A.C. 8:43G-7A.2 would set forth definitions of terms specific to proposed new Subchapter 7A, including "acute stroke," "acute care

rehabilitation," "complex stroke," "primary stroke center" and "comprehensive stroke center."

Proposed new N.J.A.C. 8:43G-7A.3 would set forth minimum requirements for primary stroke centers. N.J.A.C. 8:43G-7A.3(a)1 would articulate minimum patient care criteria, including staffing standards for an acute stroke team that would be available 24 hours a day, seven days a week that would be able to see an emergency department patient within 15 minutes of arrival in the emergency room, or within 15 minutes following a diagnosis of a patient's potential acute stroke. Also proposed for inclusion are requirements for written policies and standardized (pre-printed) orders for the emergency care of stroke patients (N.J.A.C. 8:43G-7A.3(a)2). Proposed new N.J.A.C. 8:43G-7A.3(a)3 and 4 would require the maintenance of around-the-clock neuroimaging services (that is, computerized tomography and magnetic resonance imaging scanning and image interpretation availability) and laboratory services (that is, blood testing, electrocardiography and x-ray services). With the exception of residents training in an Accreditation Council of Graduate Medical Educationapproved radiology training program, board certification of the radiologists or neurologists interpreting the imaging studies would also be required (N.J.A.C. 8:43G-7A.3(a)3), as would be fully staffed intermediate and intensive care beds (N.J.A.C. 8:43G-7A.3(a)5), the provision of neurosurgical services either on-site or by agreement with a comprehensive stroke center (N.J.A.C. 8:43G-7A.3(a)6), and the provision of acute rehabilitation services (N.J.A.C. 8:43G-7A.3(a)7). Proposed new N.J.A.C. 8:43G-7A.3(a)8 would require hospitals to have signed

contractual agreements with at least one carrier that provides insurance coverage through the State Medicaid, Children's Health Care Coverage Program and FamilyCare Health Coverage Program. Proposed new N.J.A.C. 8:43G-7A-3(a)9 would require primary stroke center hospitals to have transfer agreements with a comprehensive stroke center.

Proposed new N.J.A.C. 8:43G-7A.4 would establish minimum primary stroke center staff qualifications, including the minimum qualifications for a primary stroke center director and the composition and qualifications of members of a stroke team. In all instances, stroke center staff would be required to have special training or education in stroke diagnosis and treatment. In addition, neurology and emergency department personnel as well as nursing and unlicensed assistive personnel assigned to intermediate or intensive care beds utilized for stroke patients would be required to be trained and experienced in caring for acute stroke patients (N.J.A.C. 8:43G-7A.4(d) and (e)).

Proposed new N.J.A.C. 8:43G-7A.5 would set forth the education and training that would have to be provided to personnel furnishing direct patient care to acute stroke patients in hospitals designated as primary stroke centers.

Designated hospitals, through a stroke center director, would also be required to provide education and training for a hospital's emergency personnel, as well as education for the public, about stroke issues, including prevention, diagnosis and treatment.

Proposed new N.J.A.C. 8:43G-7A.6 would require a primary stroke center to have and maintain a database to support evaluation of outcomes and

continuous quality improvement. As proposed, the database or registry would include at least the number of patients evaluated, the number of patients receiving acute interventional therapy, the amount of time from patient presentation to delivery of acute interventional therapy, and patient length of stay, functional outcome, morbidity and discharge disposition.

Proposed new N.J.A.C. 8:43G-7A.7 would establish minimum requirements for comprehensive stroke center staffing, policies and procedures. In addition to compliance with primary stroke center standards as set forth at proposed new N.J.A.C. 8:43G-7A.3 and 4, comprehensive stroke centers would be required to maintain a neurosurgical team capable of assessing complex stroke and stroke-like syndromes that would be available either on-site or on-call in accordance with the emergent on-call requirements set forth at N.J.A.C. 8:43G-5.1(I)2; and maintain on staff a qualified neuroradiologist and a physician with neuro-interventional angiographic training and skills that would be available either on-site or on-call in accordance with the emergent on-call requirements set forth at N.J.A.C. 8:43G-5.1(I)2. Comprehensive stroke centers would also be required to provide inpatient comprehensive rehabilitation services either on-site or by written transfer agreement with another health care facility (N.J.A.C. 8:43G-7A.7(a)3), and to maintain written transfer agreements with primary stroke centers to accept complex stroke patients (N.J.A.C. 8:43G-7A.7(a)4). In addition, the proposed new rules would require that comprehensive stroke centers provide support services that would include: magnetic resonance imaging and computed tomography angiography capabilities, and digital subtraction angiography with a

special procedures suite equipped for neuro-interventional procedures (N.J.A.C. 8:43G-7A.3(a)3i and 7.7(a)2. The Department believes that the standards proposed for comprehensive stroke centers would ensure such centers have the capability to provide the most appropriate care and services to patients with complex stroke.

Proposed new N.J.A.C. 8:43G-7A.8 would set forth comprehensive stroke center education and training requirements that would include: the provision of guidance and continuing medical education to primary stroke centers, minimum annual continuing stroke education, provision of graduate medical education in stroke, and the conducting of research on stroke related topics such as laboratory research, clinical drug studies or both.

Proposed new N.J.A.C. 8:43G-7A.9 would set forth the requirement that comprehensive stroke centers have a continuous quality improvement program, as would be required of primary stroke centers at N.J.A.C. 8:43G-7A.6. In addition, comprehensive stroke centers would be required to develop and maintain sophisticated outcomes assessment and performance improvement capability that incorporates data from affiliated primary stroke centers and integrates regional, State and national data.

Proposed new N.J.A.C. 8:43G-7A.10 would set forth licensing, compliance and fair hearing requirements for the retention of stroke center designation, including hospital corrective action and appeal processes.

The Department is also proposing to amend N.J.A.C.8:43G-12,

Emergency Department and Trauma Services. N.J.A.C. 8:43G-12.7(c) requires

The official version of any departmental rulemaking activity (notices of proposal or adoption) are published in the *New Jersey Register* or *New Jersey Administrative Code*. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.

hospitals to perform appropriate medical screenings when individuals present and request examination or treatment (or when such a request is made on the individual's behalf). The proposed amendment to N.J.A.C. 8:43G-12.7(c) would require hospitals to develop and implement policies and procedures for the evaluation and treatment of those patients who may have a diagnosis of stroke and the implementation of a stroke team and treatment protocols in accordance with the new stroke center rules contained in this proposal (N.J.A.C. 8:43G-7A). The Department is proposing the amendment to N.J.A.C. 8:43G-12.7(c) in an effort to increase the likelihood that patients with acute stroke symptoms would be recognized and treated earlier, and transferred to primary or comprehensive stroke centers so that they may obtain the most appropriate available care in as timely a manner as possible.

A new paragraph at N.J.A.C. 8:43G-12.7(c)1 requires that all medical screenings designed to identify patients presenting with stroke symptoms to be performed by qualified medical personnel. In the event that the hospital is designated as either a primary or comprehensive stroke center, any patient with a clinical suspicion of stroke shall be evaluated by the stoke team consistent with the hospital's stroke treatment protocols. The Department believes the proposed amendment is consistent with the intent of the Act. New N.J.A.C. 8:43G-12.7(c) 1 and 2 require that all medical screenings designed to identify patients presenting with stroke symptoms to be performed by qualified medical personnel. In the event that the hospital is designated as either a primary or comprehensive

stroke center, any patient with a clinical suspicion of stroke shall be evaluated by the stroke team consistent with the hospital's stroke treatment protocols.

Because the Department has provided a 60-day comment period for this notice of proposal, this notice is excepted from the calendar requirement set forth at N.J.A.C. 1:30-3.3(a)5.

## Social Impact

The Legislative intent of the Act is to optimize treatment and care environments for New Jersey residents who have a stroke. The Department's intent in proposing these new rules and amendment is to implement the provisions of the Act, consistent with the Legislative intent. Research suggests that appropriate utilization of primary stroke centers, including the provision of educational services to the community, has the potential to improve patient care, reduce patient morbidity as well as mortality resulting from stroke, result in fewer peristroke complications, improve the long-term outcomes for stroke patients, and result in increased patient satisfaction generally.

Comprehensive stroke centers, which the Department believes are intended to address the needs of patients presenting with complex strokes, would offer more specialized care than primary stroke centers. The term "complex stroke," as proposed for definition at N.J.A.C. 8:43G-7A.2, refers to situations in which a patient believed to be having an acute stroke also has one or more specific co-morbid conditions, thereby complicating the provision of efficient and effective treatment. In order to provide optimal treatment for

patients with complex strokes, it would be necessary for the hospital to have a different array of services readily available, some of which are very specialized.

The proposed rules and amendment would establish standards that would promote the provision of quality care, while allowing for advances in treatment through education, and technological innovations, so that the designated stroke centers would be able to respond to the increasingly rapid changes occurring nationally in the treatment of stroke. The Department anticipates that the proposed new rules and amendment, by which the Department would designate hospitals as primary or comprehensive stroke centers, would have a positive social impact in New Jersey, because of the increased ability of hospitals to deliver the most appropriate services in as timely a manner as possible to stroke victims, maximizing the potential for recovery, which is in the best interests of all concerned.

# **Economic Impact**

The Department is not in a position to determine the economic impact upon any particular party as a result of the proposed new rules or amendment, particularly because designation as a stroke center is voluntary. However, the Department believes that the overall economic impact would be positive, notwithstanding that it is likely that some hospitals would incur some expenses in trying to meet the proposed designation standards, or in complying with the proposed amendment at N.J.A.C. 8:43G-12.7(c). Hospitals electing to become designated as primary or comprehensive stroke centers may incur expenses

related to staffing, equipment, facility, training, education and community outreach, but the actual expenses involved would vary from one hospital to another based on their current resources, and the designation that each hospital decides to seek. According to the American Stroke Association, the range of costs for establishing and maintaining a primary stroke center could be from \$8,000 to \$200,000, depending on current staffing levels and the presence of various programs and infrastructure. Some of these expenses would be offset by the grants the Department is authorized to provide to hospitals needing financial assistance to meet the primary or comprehensive stroke center designation. Depending upon the hospital and its marketing goals, the intrinsic value of the designation may more than offset any expenses involved in obtaining and maintaining the designation.

From the perspective of the patients who obtain treatment from designated stroke centers, the cost savings could be substantial, not only in terms of reducing the actual expenses for treatment of the stroke, but potentially reducing other expenses related to accommodations that may be required as a result of stroke complications. Currently, the average lifetime cost of a stroke is about \$100,000, according to the American Stroke Association. <sup>2</sup> The Department expects the resulting stroke center designations based on the proposed amendment and new rules would have a positive economic impact upon the health care delivery system, the health and disability insurance

<sup>&</sup>lt;sup>1</sup> "Recommendations for the Establishment of Primary Stroke Centers." Journal of the American Medical Association, June 21, 2000, Vol. 283, No. 23, P. 3107

<sup>&</sup>lt;sup>2</sup> Ibid, p. 3102

The official version of any departmental rulemaking activity (notices of proposal or adoption) are published in the *New Jersey Register* or *New Jersey Administrative Code*. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.

systems, patients, State and Federal assistance programs, as well as employers, if victims of stroke are able to access more specialized and efficient treatment that has the potential to return patients to fuller functioning capacity more often and more quickly.

## Federal Standards Statement

The proposed amendment and new rules would not impose standards on hospitals in New Jersey that exceed those contained in Federal law or regulation. Since there is currently no Federal regulation governing stroke centers, as described herein, a Federal standards analysis is not necessary for these proposed new rules and amendments.

## Jobs Impact Statement

The Department does not expect that the proposed amendment and new rules would increase or decrease the number of jobs available in licensed health care facilities.

#### Agriculture Industry Impact

The proposed amendment and new rules would have no impact on the agriculture industry in New Jersey.

## Regulatory Flexibility Statement

The proposed amendment and new rules would impose requirements only on licensed general hospitals licensed in New Jersey, which are not considered to be "small businesses" within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., as each employs more than 100 people full-time. Therefore, the proposed amendment and new rules would impose no compliance, reporting or recordkeeping requirements on small businesses, and no regulatory flexibility analysis is necessary.

## **Smart Growth Impact**

The proposed amendment and new rules would have no impact upon the achievement of smart growth and implementation of the State Development and Redevelopment Plan.

<u>Full text</u> of the proposal follows (additions indicated in boldface thus; <u>SUBCHAPTER 7A. STROKE CENTERS</u>

#### 8:43G-7A.1 Stroke center standards; scope

This subchapter sets forth the standards for designation as a primary or comprehensive stroke center with which all applicants for the respective designations shall comply.

#### 8:43G-7A.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings:

"Acute care rehabilitation" means the provision of occupational therapy,
physical therapy and speech-language pathology, as medically necessary, during
the acute phase of a stroke patient's hospital stay.

"Acute stroke" means the rapid onset of a focal neurological deficit with signs or symptoms persisting longer than 24 hours and not otherwise attributable to another disease process. The term "acute stroke" includes the subtype acute hemorrhagic stroke and the subtype acute ischemic stroke.

"Complex stroke" means a stroke occurring in a person who also suffers
from one or more of the following co-morbid conditions:

- 1. Any previous ipsilateral surgery or intervention;
- 2. Any previous ipsilateral stroke or intervention;
- Known history of vascular disease or major vascular surgery within two years;
- 4. Severe (symptomatic) chronic obstructive pulmonary lung disease;
- 5. Class III or IV cardiac symptoms, or previous cardiac bypass surgery; or
- 6. History of radiation or any prior (even non-vascular) surgery to the neck.

"Comprehensive stroke center" means a licensed general hospital

designated to evaluate, stabilize and provide emergency care to patients with

acute stroke symptoms, that has the capability to provide specialized care to

patients with complex strokes, including patients with acute stroke symptoms transferred from other general hospitals.

"Primary stroke center" means a licensed general hospital designated to evaluate, stabilize and provide emergency care to patients with acute stroke symptoms, and to admit such patients for inpatient services as appropriate to the needs of the patient, but which has limited capacity to provide inpatient care to patients with a complex stroke.

## 8:43G-7A.3 Primary stroke center licensure designation

- (a) To be designated as a primary stroke center, a hospital shall, at a minimum, provide:
- 1. An acute stroke team available to see a patient identified as a potential acute stroke patient within 15 minutes following the patient's arrival at the hospital's emergency department or within 15 minutes following a diagnosis of a patient's potential acute stroke;
- 2. Written policies and procedures for stroke services that are reviewed at least every three years, revised more frequently as needed, and implemented.

i. These policies and procedures shall include written protocols and standardized orders for emergency care of stroke patients;

3. Neuro-imaging services capability that is available 24 hours a day, seven days a week, such that imaging shall be performed within 25 minutes following order entry. Such studies shall be interpreted by a board-certified

radiologist, board-certified neurologist or residents who interpret such studies as part of their training in an Accreditation Council of Graduate Medical Education-approved radiology training program within 20 minutes of study completion.

i. Neuro-imaging services shall, at a minimum, include computerized tomography scanning or magnetic resonance imaging, as well as interpretation of the imaging.

ii. In the event that tele-radiology is used in image interpretation, all staffing and staff qualification requirements contained in this subchapter shall remain in effect and shall be documented by the hospital.

iii. For the purpose of this subsection, a qualified radiologist shall be board-certified by the American Board of Radiology or the American Osteopathic Board of Radiology.

iv. For the purpose of this subsection, a qualified neurologist shall be board-certified by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry;

4. Laboratory services capability 24 hours a day, seven days a week, such that services may be performed within 45 minutes following order entry.

<u>i. Laboratory services shall, at a minimum, include blood</u> <u>testing, electrocardiography and x-ray services;</u>

5. Intermediate, telemetry or critical care beds staffed in accordance with N.J.A.C. 8:43G-9.20 and 9.7, respectively;

The official version of any departmental rulemaking activity (notices of proposal or adoption) are published in the *New Jersey Register* or *New Jersey Administrative Code*. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.

- 6. Neurosurgical services that are available, including operating room availability, either directly or under agreement with a comprehensive stroke center, within two hours following admission of acute stroke patients to the primary stroke center;
  - 7. Acute care rehabilitation services;
- 8. Documentation that it has current contractual agreements with at least one carrier that provides health insurance coverage through the State

  Medicaid Children's Health Care Coverage Program, established pursuant to

  N.J.S.A. 30:4I-1 et seq., and the New Jersey FamilyCare Health Coverage

  Program, established pursuant to N.J.S.A. 30:4J-8 et seq.; and
- 9. Transfer arrangements with a comprehensive stroke center in

  New Jersey that facilitate transfer of patients with complex strokes to the

  comprehensive stroke center for care when clinically warranted.
- 8:43G-7A.4 Primary stroke center staff qualifications
- (a) There shall be a physician director of a primary stroke center, who may also serve as a physician member of a stroke team, who is board-certified in neurology or neurosurgery and who shall meet two or more of the following qualifications:
  - 1. Completion of a stroke fellowship;
- 2. Participation (as an attendee or faculty) in at least two regional, national or international stroke courses or conferences each year;

- 3. Authorship of five or more peer-reviewed publications on stroke; and/or
- 4. Eight or more continuing medical education (CME) credits each year in the area of cerebrovascular disease.
  - (b) At a minimum, an acute care stroke team shall consist of:
- 1. A neurologist or emergency physician who is board-certified or board-eligible in neurology or emergency medicine with special competence in caring for acute stroke patients; and
- 2. A registered nurse, physician assistant or nurse practitioner who has demonstrated competency, as determined by the physician director described in (a) above, in caring for acute stroke patients.
- (c) Each physician member of a stroke team, except residents functioning under supervision as part of the hospital's graduate residency training program, shall meet one or more of the following qualifications:
  - 1. Completion of a stroke fellowship;
- 2. Participation (as an attendee or faculty) in at least two regional, national or international stroke courses or conferences each year;
  - 3. Authorship of five or more peer-reviewed publications on stroke;
- 4. Eight or more CME credits each year in the area of cerebrovascular disease.

or

- (d) Neurology and emergency department personnel shall be trained in the diagnosis and treatment of acute stroke in accordance with the training and education requirements set forth in N.J.A.C. 8:43G-7A.5(a)1.
- (e) Nursing staff and unlicensed assistive personnel assigned to intermediate or telemetry or critical care beds utilized for acute stroke patients shall be trained and experienced in caring for acute stroke patients in accordance with the training and education requirements set forth in N.J.A.C. 8:43G-7A.5(a)1.

## 8:43G-7A.5 Primary stroke center education and training

- (a) A hospital designated as a primary stroke center shall, under the direction of a stroke center physician director, provide education regarding acute stroke to both the hospital's personnel and the public.
- 1. The hospital shall provide to personnel engaged in direct patient care of acute stroke patients continuing education annually regarding diagnosis and treatment of acute stroke as follows:

i. For those personnel who are assigned to an acute stroke team, a minimum of eight CME credits or eight continuing education units (CEU) or eight hours of training for unlicensed assistive personnel, as applicable, each year in the area of cerebrovascular disease; and

ii. For those personnel who are not assigned to a stroke team but are regularly assigned to the care of acute stroke patients, a minimum

The official version of any departmental rulemaking activity (notices of proposal or adoption) are published in the *New Jersey Register* or *New Jersey Administrative Code*. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.

of four CME credits or four CEU or four hours of training for unlicensed assistive personnel, as applicable, each year in the area of cerebrovascular disease.

2. The hospital shall provide to the public ongoing education regarding prevention, recognition, diagnosis and treatment of acute stroke, hosting at least two such programs annually.

## 8:43G-7A.6 Primary stroke center continuous quality improvement

- (a) A hospital designated as a primary stroke center shall collect patientlevel data to support evaluation of outcomes and quality improvement activities.
- 1. Data shall be collected on each patient evaluated for stroke and each patient receiving acute interventional therapy.
  - (b) The hospital shall track, at a minimum:
- 1. The number of patients evaluated for acute stroke and transient ischemic attacks;
  - 2. The number of patients receiving acute interventional therapy;
- 3. The amount of time from patient presentation to delivery of acute interventional therapy;
  - 4. Patient length of stay;
- 5. Patient functional outcome at time of discharge from the acute care facility;
  - 6. Patient morbidity; and
  - 7. Discharge disposition.

- (c) Every primary stroke center shall maintain the data required in (a) and (b) above in a database or registry capable of tracking patient outcomes.
- 1. The hospital shall have written policies regarding ongoing evaluation of the data and implementation of quality improvement activities based on data evaluation.

# 8:43G-7A.7 Comprehensive stroke center staffing

- (a) In addition to meeting the requirements of N.J.AC. 8:43G-7A.3 and 7A4, a hospital designated as a comprehensive stroke center shall:
- 1. Satisfy the following staff qualifications, consistent with the oncall criteria set forth at N.J.A.C. 8:43G-5.1(I)2:

i. A neurosurgical team capable of assessing and treating complex stroke and stroke-like syndromes;

ii. A neuroradiologist with current Certificate of Added

Qualifications in neuroradiology on staff;

iii. A physician with neuro-interventional angiographic training and skills on staff as deemed by the hospital's credentialing process;

2. Have available 24 hours a day, seven days a week, digital subtraction angiography and a special procedures suite equipped for neurointerventional procedures, such that the procedures shall be performed within 20 minutes following order entry.

The official version of any departmental rulemaking activity (notices of proposal or adoption) are published in the *New Jersey Register* or *New Jersey Administrative Code*. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.

i. In the event that tele-radiology is used in image interpretation, all staffing and staff qualification requirements contained in this subchapter shall remain in effect and shall be documented by the hospital.

ii. A qualified radiologist shall be board-certified by the

American Board of Radiology or the American Osteopathic Board of

Radiology.

iii. A qualified neurologist shall be board-certified by the

American Board of Psychiatry and Neurology or the American Osteopathic Board

of Neurology and Psychiatry;

- 3. Provide comprehensive rehabilitation services either on site or by written transfer agreement with another health care facility licensed to provide such services; and
- 4. Enter into and maintain written transfer agreements with primary stroke centers in New Jersey to accept transfer of patients with complex strokes when clinically warranted.

8:43G-7A.8 Comprehensive stroke center education and training

- (a) In addition to satisfying the requirements of N.J.A.C. 8:43G-7A.5, a hospital designated as a comprehensive stroke center shall:
- 1. Provide guidance and continuing medical education to hospitals designated as primary stroke centers with which they have transfer agreements;
  - 2. Provide graduate medical education in stroke; and

3. Conduct research on stroke-related topics, such as laboratory research or clinical drug studies or both.

8:43G-7A.9 Comprehensive stroke center continuous quality improvement

A hospital designated as a comprehensive stroke center shall, in addition to satisfying the requirements of N.J.A.C. 8:43G-7A.6, develop and maintain deidentified outcomes data from affiliated primary stroke centers and shall integrate this data and its own patient-level data with available regional, State and national data in order to develop benchmarks for performance to be used in assessing and improving quality in the hospital and its affiliated primary stroke centers.

## 8:43G-7A.10 Licensing and compliance

- (a) General hospitals seeking designation as a primary stroke center or a comprehensive stroke center shall meet the applicable minimum criteria and standards contained in this subchapter and file a licensing amendment in accordance with N.J.A.C. 8:43G-2.2.
- (b) Existing designated primary and comprehensive stroke centers shall continue to meet the minimum criteria and standards contained in this subchapter on an annual basis.
- (c) In accordance with N.J.S.A. 26:2H-12.28d, failure to comply with the provisions of this subchapter may result in suspension or revocation of the hospital's stroke center designation or other enforcement action in accordance with N.J.A.C. 8:43E.

8:43G-12.7 Emergency department patient services

- (a) (b) (No change.)
- (c) If an individual comes to the emergency department requesting examination or treatment for a medical condition, or if a request is made on the individual's behalf, the hospital shall provide for an appropriate medical screening examination performed by qualified medical personnel. Medical screening may be provided in the emergency department or urgent care clinic or area accessible to the emergency department and on hospital grounds.
- 1. Qualified medical personnel shall perform all medical screenings designed to identify patients clinically suspected of presenting with a stroke.
- 2. If the hospital is a designated primary or comprehensive stroke center, whenever a clinical suspicion of stroke exists, the stroke team shall further evaluate the patient consistent with the stroke treatment protocols established by the hospital as required for designation in accordance with

N.J.A.C. 8:43G-7A.

(d) - (z) (No change.)

# INFORMATIONAL COPY ONLY. THE NEW JERSEY REGISTER IS THE OFFICIAL JOURNAL OF STATE AGENCY RULEMAKING